THE MEDICAL DEVICE REGULATORY MODERNIZATION ACT OF 1997

HON. ANNA G. ESHOO

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Ms. ESHOO. Mr. Speaker, I'm pleased to join with my colleague from Texas, Mr. BARTON, to introduce the Medical Device Regulatory Modernization Act of 1997.

Since coming to Congress over 4 years ago, I have heard a consistent message from medical device companies in my district—the Food and Drug Administration is not keeping up with innovation. Companies were asking for congressional action to help modernize FDA's regulatory process.

The bipartisan legislation we are introducing today accomplishes that goal.

We've had testimony before the Commerce Committee that the agency lacks the resources to keep up with its workload and as a result reviews were taking too long.

The Barton/Eshoo bill frees up FDA resources by allowing for independent review for class I and class II devices that are not implantable or likely to cause serious harm if they fail. Class I and class II devices are relatively less complex, ranging from surgical gloves and syringes to MRI machines. By increasing the use of third parties for lower risk devices, the agency will be able to focus their attention on higher risk, more complicated products that demand greater resources and time.

We were told that a chasm of communication exists between medical device companies and the FDA.

Under our legislation, FDA will be required to meet with applicants at their request both during the investigational device exemption phase and early on in the product review stage. It is hoped that through this increased communication, there will be a greater understanding on the part of the applicant as to what the agency will require for approval, and a greater understanding by the agency of the technology being employed by the applicant.

We heard that the FDA needs to recognize national and international performance standards to cut down on paperwork and redundant reporting requirements.

The bill allows the FDA to recognize national and international standards and allows companies to self-certify to these standards. There are penalties for the falsification of data and all certification information is available at FDA's request.

Last, companies have raised concerns that in reviewing applications, FDA has, in the past, required information from companies that is outside the scope of the application.

The bill makes clear that it is FDA's job to review applications for substantial equivalence, for lower risk devices, or safety and effectiveness, for higher risk devices. The agency is not charged with reviewing relative effectiveness, which should be determined by the marketplace, or for reviewing items outside the proposed intent of the device; as long as the public health is not at risk.

These are some of the key provisions of the legislation, but they are by no means the only important provisions in this bill. There are 22 sections to the legislation that address issues including cost market surveillance, dispute resolution, humanitarian use of devices, device tracking and regulatory harmonization to name a few. It is a comprehensive approach to modernizing the way the FDA regulates medical devices.

Representative BARTON and I have worked very hard to ensure that this bill moves the agency forward. It's a positive blueprint to strengthen the FDA's oversight of the public health. I believe it will help the agency review products more efficiently and improve communications between FDA and industry, brining new products to market and to the patients that urgently need them.

I urge my colleagues to support it.

IN MEMORY OF HAZEL SCHWEIRKING GRAFFEO

HON. MARCY KAPTUR

OF OHIO

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Ms. KAPTUR. Mr. Speaker, I rise today to pay tribute to a remarkable woman from my district. Hazel Schweirking Graffeo of Oregon, OH passed away on Tuesday, April 29, 1997. Mrs. Graffeo fought a very courageous 8 year battle with cancer. Although that battle cost her dearly, she never lost her spirit.

Mrs. Graffeo was devoted to her husband and family, and enjoyed cooking for them. She also loved entertaining for others. She was a fan of big band music and enjoyed dancing. She loved reunions and other family activities.

Mrs. Graffeo's generous heart extended beyond her family and friends. She was an active member in the Alba Club, the Oregon Democratic Club, St. Charles Hospital Auxiliary, VFW Post 9816, and St. John Lutheran Church in Williston, OH. Everywhere, she exuded good cheer, strong values, and made others feel welcome.

Mrs. Graffeo is survived by her husband Joe and daughters Sharon, Janet, Janice, and Carolyn, as well as 12 grandchildren and 12 great-grandchildren. Our sympathies and prayers are with them, but we know that the memory and example set by Hazel Graffeo will give them a measure of comfort. Even as they mourn their loss, may they celebrate her life.

SUPPORT FOR THE DRUG FREE COMMUNITIES ACT OF 1997

HON. BERNARD SANDERS

OF VERMONT

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Mr. SANDERS. Mr. Speaker, I rise today in support of the Drug Free Communities Act of 1997, legislation which supports communities across the Nation in their efforts to reduce rising teenage drug abuse. Studies show that teenage use of marijuana, inhalants, cocaine, methamphetamine, LSD, heroine, and other drugs is on the increase—and it is among children that we are seeing the greatest increase in use. The Drug Free Communities Act of 1997 is an important step toward empowering communities to fight the growing phenomenon of drug abuse among our Nation's youth.

I would like to add that I very much appreciate that the original cosponsors of this bill, Mr. PORTMAN, Subcommittee Chairman HASTERT, Mr. LEVIN, and Mr. RANGEL, as well as the subcommittee ranking member, Mr. BARRETT, were very willing to work with me to mold this legislation so that rural communities, as well as urban communities, are given the same chance to benefit from this Federal program. Because of our discussions, this bill now provides that antidrug coalitions in rural communities, communities under 30,000 people, will be given the opportunity to receive up to $100,000 in Federal matching funds. This puts rural communities at the same level as urban communities for receiving Federal matching funds.

Mr. Speaker, let me emphasize that drug abuse is not only an urban problem, but is also a problem in the rural communities of this country. Drug pushers find a market for their drugs, not only in the schools of urban areas, but also in the schools of our rural areas. We are beginning to see gang activity in our rural communities and these gangs are largely centered around drug use. Presently, it is our rural areas which are ill-equipped to handle an influx of drugs because rural areas do not have access to the local resources which urban areas enjoy. Because of bipartisan cooperation which has taken place, rural antidrug coalitions will be better able to deal with drug abuse problems.

Again, I thank the gentlemen for their cooperation and willingness to accept my input on this bill, and I urge passage of this important legislation.

SMALL BUSINESS REMEDIATION ACT

HON. JOE BARTON

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Mr. BARTON of Texas. Mr. Speaker, I rise today to introduce a bill which will help improve the environment while protecting small businesses. This bill, the Small Business Remediation Act, will enable the Nation's 30,000 dry cleaners, their employees, neighbors, and customers to improve the local environment while preserving the dry cleaners' ability to preserve businesses and remain vital contributors to their communities. The bill has bipartisan support in Congress and tremendous nationwide support from the dry cleaning industry, and I urge the House to pass the legislation.

For the last few years dry cleaners, one of the largest groups of small businesspeople in America, have faced substantial potential liability associated with the remediation of soil surrounding some dry cleaning businesses. This potential liability has resulted in the small business owners in the industry having trouble obtaining or renewing leases and borrowing money, or even risk bankruptcy.

This potential liability is being greatly compounded by the misapplication of the Federal drinking water standard to soil remediation projects. This makes no sense, of course, but this standard is being used by States which are overseeing the remediation of some dry cleaning sites mostly because there is no other standard readily available.

The Federal drinking water standard for the relevant compound—perchlorethylene or